UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Trumbull, Ohio v. Purdue Pharma, L.P. et al.*, Case No. 18-op-45079; *The County of Lake, Ohio v. Purdue Pharma L.P., et al.*, Case No. 18-op-45032 Track 3	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

PHARMACY DEFENDANTS' OBJECTIONS TO PLAINTIFFS' RESPONSE TO THE COURT'S REQUEST FOR INPUT REGARDING STATUTES AND REGULATIONS TO BE QUOTED IN JURY INSTRUCTIONS

I. THE COURT SHOULD REJECT BOTH PLAINTIFFS' PREMATURE AND ERRONEOUS PROPOSED INSTRUCTION AND THEIR INVITATION TO READ CHERRY-PICKED PORTIONS OF STATUTES AND REGULATIONS TO THE JURY

Plaintiffs' response to the Special Master's request for input regarding statutes and regulations to be quoted in jury instructions, Dkt. 3548 ("Submission"), makes one thing clear: all parties agree that reading statutes to the jury is inappropriate. *Compare* Submission at 1 *with*

Dkt. 3550 at 1-2. The reasons for the parties' objections to reading statutes, however, are different.

Pharmacy Defendants oppose reading statutory language to the jury for two fundamental reasons. First, as explained in prior submissions to the Court as well as Section II of this Objection, Plaintiffs' legal theories based on the Controlled Substances Act ("CSA") and related Ohio law are invalid for a variety of reasons. Second, even if Plaintiffs had a valid legal theory based upon those statutes and regulations,[1] it is not the jury's province to interpret the purported duties that any statute or regulation imposes on Pharmacy Defendants. Instead, it is the *Court's* duty to determine the elements of a violation and instruct the jury regarding those elements.

By contrast, Plaintiffs oppose reading statutes and regulations to the jury so that, instead, the Court reads a paraphrased version of them, effectively adding legal duties and prohibitions that are not found anywhere in federal or Ohio law. They must take such a position, because the statutes and regulations upon which they rely do not actually include the language essential to their theories of both distributing and dispensing liability. Should the Court read the text of the relevant laws to the jury, Plaintiffs ask the Court to cherry pick Plaintiffs' preferred phrases, omit less-favorable text or context, and then string those cherry-picked, out-of-context quotations together in a misleading manner. The Court should reject both of Plaintiffs' suggested approaches.

A. The Court Should Reject Plaintiffs' Incorrect and Premature Proposed Jury Instruction

Although the Court requested a list of statutes and regulations to be read to the jury, Plaintiffs responded with a lengthy proposed jury instruction. This request is premature, filed

[1] By referring to regulations, the Pharmacy Defendants do not waive, and hereby reassert, their objection to consideration of any regulation as a basis for finding unlawful conduct. *See, e.g.,* Dkt. 3340.

well before the relevant deadlines for proposing jury instructions in advance of trial. Those deadlines are closer to trial for a reason: they allow the parties and the Court the benefit of reviewing the legal arguments in light of more developed evidence and with the benefit of more briefing and associated rulings on major motion practice and key evidentiary issues. Pharmacy Defendants object to Plaintiffs' proposed instruction in multiple respects and will submit a more appropriate and legally correct proposed instruction regarding statutory and regulatory requirements by July 1, consistent with the Track 3 scheduling order. Dkt. 3595. In the meantime, the Court should reject Plaintiffs' proposed jury instruction in its entirety and only consider the parties' proposed instructions simultaneously during the pre-trial period when the Court has ordered such instructions to be submitted.

Pharmacy Defendants also object to Plaintiffs' proposed jury instruction because it is legally erroneous. Plaintiffs suggest that the Court inform the jury of the requirements of the CSA by means of an instruction that inaccurately states almost every legal standard it discusses. *See* Submission at 3-4. For example, as explained more fully in Section II, Plaintiffs' proposed instruction does not quote any of the relevant statutory language concerning the duties the CSA places on pharmacists, but erroneously states that "[a] pharmacy" may not fill a prescription that "it knows *or has reason to know* is invalid[.]" Submission at 4 (emphasis added). But it is the pharmacist, not the pharmacy, who determines whether to dispense a controlled substance, and the party on whom the law places a "corresponding responsibility." *See* 21 C.F.R. §1306.04(a). And the pharmacist acts unlawfully under the plain language of federal regulations only if she *knows* that a prescription is invalid. As explained more fully in Section II(A)(2), the instruction also directly (and erroneously) states that the CSA imposes a duty not to ship any order a SOM system identifies as "suspicious." Submission at 3. Plaintiffs do not quote any statutory text

purportedly establishing such a duty because there is none. Indeed, even Plaintiffs acknowledge that such a duty is at best "implicit" in the regulatory requirement that a distributor design and operate a system to disclose to itself suspicious orders. Submission at 5 (discussing 21 C.F.R. §1301.74(b)). But this Court should defer ruling on these objections until the proper time; it is sufficient for now to recognize that Plaintiffs' request is premature. If the Court is inclined to take up these objections now, it should reject the Plaintiffs' proposed instructions for the reasons stated.

B. The Court Should Reject Plaintiffs' Proposed Statutory Text

As an alternative to their premature and erroneous proposed jury instruction, Plaintiffs request that the Court read out-of-context, cherry-picked portions of statutes and regulations to the jury, some of which do not even apply to the Pharmacy Defendants. Submission at 5-6. The inevitable result of that suggestion is that the jury would receive an incomplete and incorrect view of what the relevant statutes and regulations actually required of the Pharmacy Defendants, and any verdict against the Pharmacy Defendants would be fundamentally flawed. If the Court reads statutory text to the jury at all, it must provide the jury with the necessary context for all of the provisions it reads.

Each section cited in Pharmacy Defendants' submission, Dkt. 3550, provides necessary context to the jury. For example, if the Court read the jury only a portion of 21 C.F.R. § 1301.71(a), as Plaintiffs expressly request, *see* Submission at p. 7, the jury would not know that "in order to determine whether a registrant has provided effective controls against diversion" as required in that subsection, the Administrator "shall use" the "security requirements set forth in Secs. 1301.72-1301.76." And, without reading the very next subsection, 21 C.F.R. §1301.71(b), the jury could believe that strict compliance with those standards is required, when in fact, the regulation is explicit that "substantial compliance . . . may be deemed sufficient[.]" The jury

must also be permitted to review Sections 1031.72-1301.76 to understand what requirements Section 1301.71 is referring to as the standard for "effective controls against diversion." Yet Plaintiffs ask the Court to leave out almost all of those subsections as well. *See* Submission at 5. The effect would be to wrongly instruct the jury that lawful conduct (*i.e.,* substantial compliance with the physical security regulations) is unlawful if the jury determines that the Pharmacy Defendants' controls were—in some manner not specified in any statute or regulation—less than perfectly effective at preventing diversion.

A law cannot be interpreted accurately in a vacuum: "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dept. of Treasury*, 489 U.S. 803, 809 (1989); *see also, e.g., id.* ("Although the State's hypertechnical reading of the nondiscrimination clause is not inconsistent with the language of that provision examined in isolation, statutory language cannot be construed in a vacuum."); *Utility Air Regulatory Group v. EPA*, 573 U.S. 302 (2014) ("[R]easonable statutory interpretation must account for both the specific context in which ... language is used and the broader context of the statute as a whole" (internal quotation marks omitted)). Thus, if the Court is to ask the jury to interpret the requirements of the CSA or its implementing regulations (or state-law analogs), it must provide the jury with access to the full text of the law as required to imbue meaning and context into the portions upon which Plaintiffs rely.

Further, several of the provisions in Plaintiffs' submission simply do not apply to the Pharmacy Defendants and should not be read to the jury or incorporated into any jury instructions. For example, Ohio Admin. Code 4729-9-28(I) expressly applied only to licensing *virtual* wholesale distributors, and thus does not apply to Pharmacy Defendants. Similarly,

O.R.C. § 2925.03 expressly does not apply to owners of pharmacies or pharmacists, or licensed distributors. O.R.C. §2925.03(B).

It also bears noting that the parties agree that Court should *not* read OAC 4729:6-3-05 to the jury. *Compare* Dkt. 3550 at Ex. A (e-mail from Special Master Cohen suggesting that the parties might wish to have OAC 4729:6-3-05 read to the jury) *with* Submission at 6 (not listing 4729:6-3-05 among suggested Ohio statutes to be read to the jury) and Dkt. 3550 (same). That provision is not relevant here because, among other reasons, it did not become effective until April 2019.

If the Court is to read the statutes and regulations Plaintiffs list in their Submission (which the Pharmacy Defendants do not agree it should), it also should read each of those listed in Exhibit B to Pharmacy Defendants' Response to Special Master Cohen October 26, 2020 Request, Dkt. 3550, as well as the Ohio statutes and regulations attached as Exhibit A to this Objection to provide necessary context. It should also omit the provisions which expressly do not apply to Pharmacy Defendants.

II. PLAINTIFFS' PROPOSED INSTRUCTION IS LEGALLY ERRONEOUS

Plaintiffs' proposed instruction is premature, and the Court should not consider it until the parties have both had a chance to submit their proposed jury instructions before trial. To illustrate the risk of adopting jury instructions before important legal questions have been resolved, however, Pharmacy Defendants set forth some of the more egregious errors in those instructions below. By pointing out these errors, Pharmacy Defendants expressly do not waive any additional objections they may wish to make in the future, or those they have made previously.

A. Plaintiffs Proposed Instructions Related to Distribution Are Legally Erroneous

1. Plaintiffs' Proposed "Effective Controls" Instruction Is Erroneous

The Pharmacy Defendants object to the proposed instruction: "It is unlawful to distribute or dispense controlled substances without providing effective controls and procedures to guard against theft and diversion under both the CSA and Ohio controlled substances laws." Submission at 3. This instruction (1) asks the jury to determine a legal issue that should be within the exclusive province of the Court, (2) asks them to do so without the necessary statutory and regulatory context; and (3) wrongly implies that there is an "effective controls" requirement for dispensing, as opposed to distribution.

Plaintiffs' proposed instruction first errs in asking the jury to determine whether the Pharmacy Defendants violated a vague alleged duty under the CSA to "provid[e] effective controls and procedures to guard against theft and diversion." Submission at 3 & n. 2 (citing 21 C.F.R. § 1301.71(a)). But the scope of any duty imposed by the CSA and its regulations—as well as its state analogs—is a legal issue that the Court must determine, not the jury. In addition, Plaintiffs' proposed instruction omits that 21 C.F.R. § 1301.71(a) defines "effective controls" as specific "security requirements" in specific regulations "as standards for the physical security controls and operating procedures necessary to prevent diversion." *Id.* Subsection 1301.71(a) further mandates that: "In order to determine whether a registrant has provided effective controls against diversion, the Administrator *shall use* the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion." (emphasis added). And, indeed, those controls listed in 21 C.F.R. §1301.71(b) as factors to be considered by DEA in assessing a pharmacy's compliance

with the CSA *all relate to the physical security of the controlled substances,* ***not*** *to the handling of suspicious orders*.[2]

Without the accompanying regulatory language, Plaintiffs' proposed instruction would permit the jury create from whole cloth a definition of "effective controls," and related, purportedly unlawful conduct, instead of using the standards articulated in the regulation. Here,

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[2] The counterpart provision of the Ohio Administrative Code during the relevant time frame (§ 4729-9-05, now repealed and replaced by § 4729:5-3-14) similarly provides:

> (A) All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion.
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> (B) Substantial compliance with the standards set forth in rule 4729-9-11 of the Administrative Code may be deemed sufficient by the state board of pharmacy after evaluation of the overall security system and needs of the applicant, licensee or registrant. In evaluating the overall security system of a licensee, registrant or applicant, the state board of pharmacy may consider any of the following factors, as deemed relevant, for compliance with security requirements:
>
> (1) The type of activity conducted;
>
> (2) Type and form of dangerous drugs handled;
>
> (3) Quantity of dangerous drugs handled;
>
> (4) Location of the premises and the relationship such location bears on security needs;
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> (5) Type of building construction comprising the facility and the general characteristics of the building or buildings;
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> (6) Type of vaults, safes, and secure enclosures or other storage system (e.g.automatic storage and retrieval system) used;
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> (7) Type of closures on vaults, safes, and secure enclosures;
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> (8) Adequacy of key control systems and/or combination lock control systems;
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> (9) Adequacy of electronic detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
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> (10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
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> (11) Adequacy of supervision over authorized employees having access to areas containing dangerous drugs;
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> (12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;
>
> (13) Availability of local police protection or of the licensee's, registrant's or applicant's security personnel, and;
>
> (14) Adequacy of the licensee's, registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.
>
> (C) When physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the licensee or registrant during normal business operation, the physical security controls shall be expanded and extended accordingly.
>
> (D) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in rule 4729-9-11 of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the state board of pharmacy. . . .

Plaintiffs' proposed instruction encourages the jury to link the obligation to provide "effective controls" solely to suspicious order monitoring rather than primarily to physical security. This understanding of "effective controls" is inconsistent with the plain language of the regulation and would permit the jury to improperly find violations without support in the language of the CSA or its regulations.

Plaintiffs' proposed instruction also omits the regulatory language stating that substantial compliance with a registrant's obligations under the regulation can satisfy a distributor's statutory duty. 21 C.F.R. § 1301.71(b). As noted above, *see supra* 4-5, that omission would instruct the jury—contrary to law—that even nonmaterial violations of the regulations are a sufficient basis for nuisance liability.[3]

The proposed instruction is also erroneous because it implies that the alleged "effective controls" requirement, which derives from regulations concerning *distribution,* also governs Pharmacy Defendants' *distribution* conduct. The CSA does not contain any such amorphous "effective controls" requirement for dispensing. Indeed, the CSA requires only wholesale distributors—not pharmacies—to monitor suspicious orders. Section 21 U.S.C. §1301.74. The Plaintiffs' proposed instruction is therefore inaccurate and confusing.

2. Plaintiffs' Proposed "No-Ship" Instruction Is Erroneous

Plaintiffs ask the Court to instruct the jury that "wholesale distributors, including the Defendants, have a legal duty to . . . (3) not to ship [suspicious orders] unless investigation first shows them to be legitimate." Submission at 3. Pharmacy Defendants object to this proposed instruction, among other reasons, because (1) no statute or regulation having the force of law

[3] CVS preserves its objection that there is no reason to refer to 21 C.F.R. § 1301.71 in the Court's instructions at all, because in its view that provision is inapplicable. *See* Dkt. 3550 at 1. However, if the regulation is mentioned to the jury, CVS agrees that it should be explained accurately.

forbids a wholesale distributor to ship an order for a controlled substance that is deemed suspicious; and (2) even if such requirement existed, the only question for a distributor would be whether the opioids contained in an order deemed suspicious likely would be diverted to the illegal marketplace, not whether the order is "legitimate" in any other sense.

First, Plaintiffs' proposed instruction states that distributors "have a legal duty . . . (3) not to ship [suspicious] orders unless investigation shows them to be legitimate." Submission at 3 & n. 3. No statute or regulation imposes any such a duty.[4] Instead, Plaintiffs' proffered "no-ship" duty originates solely in DEA guidance letters that do not have the force of law, and in administrative proceedings to revoke distributor registrations if registration is not consistent with the public interest. *See In re Nat'l Prescription Opiate Litig.,* No. 1:17-MD-2804, 2019 WL 3917575, at *4 -*6 (N.D. Ohio Aug. 19, 2019). Such revocation decisions involve fact-specific application of the public interest standard to other registrants' conduct—conduct that is markedly different from anything alleged in this case. They cannot establish a general legal duty, the violation of which is *per se* unlawful.[5]

Pharmacy Defendants recognize that in the Track 1 litigation, the Court ruled that a distributor has a duty not to fill a suspicious order unless investigation has allayed the suspicion. *In re Nat'l Prescription Opiate Litig*., No. 1:17-md-2804, 2019 WL 3917575, at *7-9 (N.D. Ohio, Aug. 19, 2019); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-cv-02804, 2019 WL

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[4] "[A]ll the regulation requires" of a distributor "with respect to suspicious orders [i]s [to] report them to the DEA." *United States v. $463,497.72 in United States Currency*, 853 F. Supp. 2d 675, 685 (E.D. Mich. 2012). Indeed, the district court noted that "the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA." *Id*. at 682.

[5] A sister district court in West Virginia reached that conclusion in refusing to remove West Virginia's action against McKesson, writing: "[T]here are no good reasons to believe that the letters have any binding effect upon distributors. . . . The agency itself . . . has found that the letters were 'not intended to have binding effect but were simply warning letters.'" *State of W. Virginia ex rel. Morrisey v. McKesson Corp.*, No. CV 16-1772, 2017 WL 357307, at *8 (S.D.W. Va. Jan. 24, 2017) (internal citation omitted).

2477416, at *16-18 (N.D. Ohio Apr. 1, 2019), *report and recommendation adopted in part, rejected in part*, No. 1:17-md-2804, 2019 WL 3737023 (N.D. Ohio June 13, 2019). The Court is always free to reconsider its interlocutory decisions, however, and should do so here. Fed. R. Civ. P. 54(b) ("[A]ny order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.").

The Court's prior ruling rested upon a mistaken interpretation of the D.C. Circuit's review of the DEA's decision to revoke its registration of a non-party pharmaceutical distributor. *See In re: Nat'l Prescription Opiate Litig.*, 2019 WL 3917575 at *8 (N.D. Ohio Aug. 19, 2019) (citing *Masters Pharmaceutical, Inc. v. D.E.A.,* 861 F.3d 206 (D.C. Cir. 2017)). But the pharmacy at issue in *Masters Pharmaceuticals* had a no-ship duty *because a prior settlement between the distributor and the DEA imposed such a duty*. *Id.* at 213-14.[6] The D.C. Circuit had no opportunity in *Masters Pharmaceuticals* to consider whether, absent such an agreement, a distributor would have a duty to refuse to fill an order that had been flagged as suspicious, or what statute or regulation might impose such a duty.[7]

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[6] The court recognized that the Administrator "concluded that Masters' frequent violations of the Reporting Requirement warranted revocation of Masters' certificate of registration ... [and] therefore had no need to consider whether Masters additionally violated the Shipping Requirement." *Masters*, 861 F.3d at 215. Because "the Administrator's holding rests on Masters' violation of the Reporting Requirement, not the Shipping Requirement," the court did not consider Masters' argument that DEA had "unlawfully ... amended the regulatory scheme by tacking the Shipping Requirement onto the settled list of 'security requirements' stated in sections 1301.72–1301.76." *Id.* at 221–22.

[7] The D.C. Circuit cited an earlier DEA administrative revocation decision as establishing a general "Shipping Requirement." 816 F.3d at 213 (citing *Southwood Pharm., Inc.,* 72 Fed. Reg. 36,487, 36,500 (Drug Enf't Admin. July 3, 2007). But that *dicta* is neither binding nor accurate. *Southwood Pharmaceuticals* does not set out a general Shipping Requirement, much less identify a basis for such a requirement in a statute or regulation. The DEA decision does lay out Southwood's egregious conduct in consistently shipping controlled substances to internet pharmacies despite abundant grounds for believing the orders were intended for unlawful use. But that discussion of Southwood's flagrant and at least willfully blind facilitation of illegal sales was relevant to the overarching question

Developments since the Court's opinion provide even more persuasive reason to reconsider and revise its prior opinion. A proposed amendment to the CSA currently pending in Congress, the recently introduced H.R. 3878 (the Block, Report, and Suspend Suspicious Shipments Act of 2020) would "create *additional requirements* for drug manufacturers and distributors who discover a suspicious order for controlled substances." H. Rept. 116-583 at 2 (emphasis added). "In addition to reporting" suspicious orders, the bill would require distributors to exercise due diligence, decline to fill the order(s), notify the DEA, and provide information on the indicators that led to the belief that filling such orders would be a violation. *Id*. The requirements would become effective six months following the enactment of the bill. *Id*. Similarly, in the Section-by-Section Analysis of the Legislation, the report notes that Section 2 amends the CSA "*to add* registrant reporting requirements regarding suspicious orders." *Id*. at 7 (emphasis added). Upon discovering a suspicious order, the registrant would be required to exercise due diligence, keep a record of the due diligence that was performed, decline to fill the order, and notify the DEA of the suspicious order and indicators giving rise to the suspicion that filling the order would be a violation of the CSA. *Id*. The proposed legislation shows that the CSA never previously imposed the "no ship" and investigatory requirements that Plaintiffs would like the Court to instruct the jury to use as a basis for liability; the new bill would *add* those duties, and would not do so until six months after it becomes law.

If that were not enough, the DEA itself has recently confirmed that existing regulations do not impose a "no ship" duty. *See* Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, 85 Fed. Reg. 69298 (proposed Nov. 2, 2020) (to be codified at 21

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whether Southwood's continued registration as a distributor was in the public interest, without regard to whether it was itself a violation of law.

C.F.R. pt. 1301). Here, DEA seeks to amend its regulations to give wholesale distributors facing a suspicious order the option to (1) "decline to distribute pursuant to the suspicious order, immediately file a suspicious order report ... , and maintain a record of the suspicious order and any due diligence related to the suspicious order" or (2) "conduct due diligence to investigate each suspicious circumstance" and, if able to dispel each such circumstance within seven days, "distribute pursuant to the order" and "maintain a record of its due diligence." Id. at 69298–99. If the existing regulations already imposed a no-ship duty, there would be no need for DEA to seek to amend its regulations to add such a duty. In light of these intervening legal developments, the Court should reconsider its prior ruling and reject Plaintiffs' proposed instruction, which would require reversal of any verdict in Plaintiffs' favor, and waste the resources the Court, the jurors, and the parties, should Plaintiffs prevail.

Second, if there were an obligation under existing regulations to investigate a potentially suspicious order before shipment (and there is not), the only question for the distributor would be whether the opioids would be likely to be diverted to the illegal marketplace, not whether the order is "legitimate" in any other sense. The DEA's second guidance letter states only that a distributor should analyze "whether the controlled substances are likely to be diverted from legitimate channels." Dkt. 2483 at 11.

Finally, the proposed instruction's reference to "wholesale distributors, including Defendants," is incorrect because none of the Pharmacy Defendants are (or, more accurately, ever were) "wholesale" distributors as that phrase is used in common parlance (*i.e.*, distributors who distribute to non-affiliated pharmacies). The distinction is critical, because those Pharmacy Defendants who self-distributed plainly had extensive knowledge of their customers, *i.e.,* their

own affiliated pharmacies. Moreover, some of the Pharmacy Defendant companies never even *self-distributed*; some of the named Pharmacy Defendants did not distribute at all.

B. The Plaintiffs' Proposed Instructions Related to Dispensing Are Legally Erroneous.

1. Plaintiffs' Proposed "Red Flags" Instruction Is Erroneous

Plaintiffs propose the instruction: "Pharmacies must maintain systems, policies or procedures to identify prescriptions that bear indicia ('red flags') that the prescription is invalid or that the prescribed drugs may be diverted for illegitimate use. Dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances." Submission at 4. The Pharmacy Defendants object to that instruction because no statute or regulation imposes any such duty. Plaintiffs rely primarily on the Court's opinion denying the motion to dismiss the Track 3 complaints. *Id.* at 4, n. 10-11. In ruling on the motion to reconsider that decision, however, the Court clarified that although it held that a pharmacy could not ignore (*i.e.*, do nothing with) data it collected, there is no statute or regulation requiring pharmacies to maintain systems of the kind described in Plaintiffs' proposed instruction. Dkt. 3499 at 6-7. And, in fact, it is not unlawful for a pharmacy not to maintain such a system. Pharmacy Defendants incorporate the arguments on this point from their briefs in support of the motion to dismiss the dispensing claim and the motion to reconsider denial of that motion. Dkts. 3340, 3379, 3439, 3468.

The only other authority Plaintiff cites for the purported "red flags" duty is O.R.C. § 4729.55(D). *See* Submission at 4, n.10. That regulation never uses the term "red flags." Far from supporting Plaintiffs' assertion that the Pharmacy Defendants are required by law to "check for and conclusively resolve red flags of possible diversion prior to dispensing," the regulation

merely requires that an applicant secure the premises such that pharmacy employees can "practice pharmacy in a safe and effective manner." *See* O.R.C. § 4729.55(D).

2. Plaintiffs' Proposed Instruction Regarding a Pharmacy's Dispensing Duty Is Erroneous

Plaintiffs propose to instruct the jury that: "A pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind to the prescription information it has, including computerized records it maintains." Submission at 3. The Pharmacy Defendants object to that proposed instruction for a variety of reasons.

To begin: "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with *the pharmacist* who fills the prescription." 21 C.F.R. §1306.04(a) (emphasis added). That "corresponding responsibility" therefore does not rest with the "pharmacy," as Plaintiffs' instruction erroneously states.

Moreover, Plaintiffs' proposed instruction would change the legal standard for liability for dispensing controlled substances. A registrant acts unlawfully only by *knowingly* filling a prescription not in the "usual course of professional treatment." 21 C.F.R. § 1306.04(a).[8] "Should know" is negligence with respect to a fact, not the actual knowledge of a fact required by the plain language of the regulation. *Global-Tech Appliances v. SEB SA*, 563 U.S. 754, 766-70 (2011). Even assuming that "knowingly" includes willful blindness, proving willful blindness requires proof of the Defendant's actual knowledge that a fact is highly likely to be true and

[8] *See* Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971) (noting that the regulation was "revised to require knowledge" after pharmacists "objected to the responsibility placed upon a pharmacist ... to determine the legitimacy of a prescription").

deliberate efforts to avoid facing the facts. Willful blindness is not the same as negligence or even recklessness about a fact. *Id.* at 770. Nor is willful blindness the same as "deliberate indifference," *id.*, which is the standard Plaintiffs' instruction implies through the use of the phrase "deliberately ignorant." See Submission at 3.

Plaintiffs' reliance on DEA letters providing guidance and administrative proceedings revoking distributor registrations is misplaced. To the extent those sources suggest a standard other than actual knowledge, the Court should disregard them. Mere guidance or interpretative proceedings cannot amend a regulation having the force of law.[9]

Finally, to the extent the Court offers a proposed instruction along this line, it must include all relevant context, including the entirety of 21 C.F.R. §1306.04(a), as well as 21 U.S.C. §§ 802(a)(10), 802(a)(21), 829(a)(1), 842(a)(1). *See* Dkt. 3550 at Ex. B.

3. Plaintiffs' Proposed Instruction Regarding the Alleged Dispensing Obligation Under Ohio Law Is Erroneous.

The Pharmacy Defendants also object to the proposed instruction that "Pharmacies also have an obligation under Ohio law to maintain adequate safeguards in their business to 'allow[] pharmacists … to practice pharmacy in a safe and effective manner.'" Submission at 4. The proposed instruction is misleading insofar as it implies a connection between O.R.C. § 4729.55(D) and the disputed obligations related to Plaintiffs' dispensing claim.

Ohio law states that as a condition of state licensure, a pharmacy must have "[a]dequate safeguards . . . that [it] will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to

[9] *See* 28 C.F.R. § 50.27(b)(1) ("guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation," and so DOJ "should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations").

practice pharmacy in a safe and effective manner." O.R.C. § 4729.55(D). The plain language of O.R.C. § 4729.55(D) refers to the protection of pharmacists and pharmacy interns who are handling drugs that may be the target of theft or robbery, and Plaintiffs cite nothing to suggest that this language has any relationship to the validity of prescriptions. Indeed, recognizing that the provision has no relevance, Plaintiffs did not even cite § 4729.55(D) as a basis for their public nuisance claims against the Pharmacy Defendants in their amended complaints. See Dkts. 3306-2. Moreover, any duty that the statute creates runs to the pharmacist and pharmacy interns, not those filling prescriptions—and much less to Plaintiffs.

Finally, § 4729.55(D) sets out no standard for the jury to apply to determine if a pharmacy is engaged in unlawful conduct**.** At best, it sets forth a condition of licensure—a licensure that was undisputedly granted for all Pharmacy Defendant pharmacies.

C. Plaintiffs' Proposed Instruction Misstates Ohio Law In Other Ways

Plaintiffs' citation to Ohio law in support of the proposed instruction is also erroneous and misleading in other ways. For example, Plaintiffs rely on O.R.C. § 2925.03, which on its terms is not applicable to pharmacies or pharmacists. *Compare* Submission at 3, n.1 *with* O.R.C. § 2925.03(B)(1) ("This section does not apply to . . . pharmacists, owners of pharmacies . . ."). Similarly, Plaintiffs support their proposed instruction with a citation to O.A.C. § 4729-9-28(I), which applied only to *virtual* wholesale distributors. *Compare* Submission at 3, n.2 *with* O.A.C. § 4729-9-28 (titled "Licensure as a virtual wholesale distributor").

D. The Jury Must Be Instructed to Separately Determine Each Alleged Violation of Ohio or Federal Law.

Plaintiffs' proposed instruction is also objectionable because it confusingly combines many different alleged violations of federal or Ohio law into a single issue. This is improper. The Court should ask the jury to make separate findings as to each alleged violation (as proposed

in Pharmacy Defendants' Track 1B proposed verdict form) so that the Court of Appeals can review the legal viability of each theory. Combining all of Plaintiffs' theories of unlawful conduct into a single undifferentiated mass will make it impossible for the Court of Appeals to evaluate which legal theory was the basis for any verdict against Pharmacy Defendants. Any verdict in Plaintiffs' favor could be overturned because of an error in a single theory.

Along the same lines, Plaintiffs' proposed instruction lumps together the duties of distributors and dispensers. For example, for CVS and Rite Aid, the legal entities that were distributors are different from the legal entity that holds the pharmacy registration. Moreover, the time period during which certain Pharmacy Defendants distributed prescription opioids is different from the time period others dispensed those medications. For all Pharmacy Defendants, the legal theories of dispensing liability and distributing liability are different, and the viability of those theories present different questions on appeal. Running those distinct theories together in the instructions is likely to lead to jury confusion about the standards applicable to the wholesale distribution and pharmacy dispensing claims. The jury should be asked to make separate findings as to dispensing and distributing.

CONCLUSION

For the foregoing reason, Pharmacy Defendants object to the Court's consideration of Plaintiffs' proposed instruction at this time as premature. They further object to the substance of the proposed instruction and to reading the cherry-picked statutory excerpts that Plaintiffs identify in their Submission. Pharmacy Defendants respectfully submit that the jury should be instructed on the elements of any "unlawful" activity on which Plaintiffs base their claim. Failing that, however, the jury should be provided the entire relevant context of the statutory

provisions at issue and should be read each and every statutory provision Pharmacy Defendants have identified.

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Respectfully submitted,

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